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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,347

01/11/2006

Thiemo Arnim Blank

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01/14/2010

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SUITE 1400

COSTA MESA, CA 92626

EXAMINER

SIMPSON, SARAH A

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

01/14/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,347	<b>Applicant(s)</b> BLANK, THIEMO ARNIM	
	<b>Examiner</b> SARAH A. SIMPSON	<b>Art Unit</b> 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/03/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

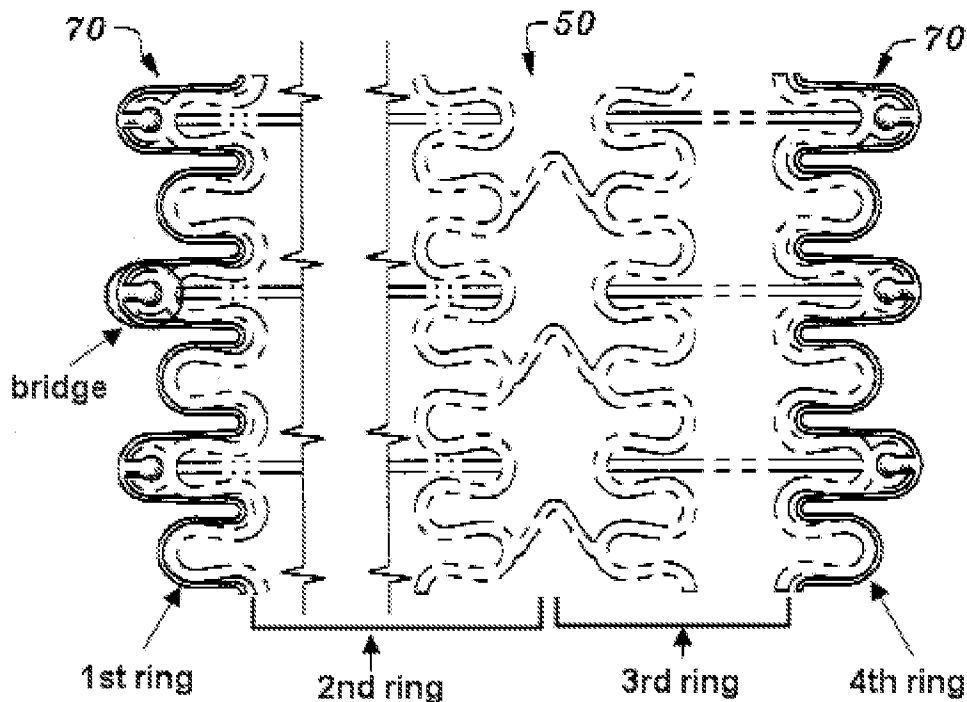
### ***Response to Arguments***

Applicant's arguments filed 10/09/2009 have been fully considered but they are not persuasive.

The Applicant argues that Frantzen does not disclose that the bridges are distributed throughout a length of the tubular structure and are instead attached to the ends of the stent. However, the stent or tubular structure as a whole includes the rings of the marker elements and the ends of the stent are also a part of the length of the tubular structure. Length is generally defined as the extent in space from one end to the other. Therefore, even if the bridges are only found on the ends of the tubular structure, they are on both the distal end and proximal end and are distributed throughout the length of the stent as shown in Figure 16. Furthermore, by being distributed circumferentially along the ends of the stent, the bridges are divided axially along the transverse longitudinal axis to provide insulated sections.

The Applicant also argues that Frantzen does not disclose that the second electrical conductivity is at least an order of magnitude lower than the first but instead discloses the opposite relationship to that which is claimed. The Examiner disagrees. Although the general stent material has a lower conductivity than the markers, the markers themselves include rings as well as bridge struts, as shown in Figure 8 reproduced below.

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Thus, the relationship between electrical conductivities of the rings is disclosed in Frantzen and there is no need to teach one of ordinary skill in the art who to arrive from a first higher conductivity to a second lower conductivity.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 25-34, 36-39, 40-43, 44-48, and 50-53** rejected under 35 U.S.C. 103(a) as being unpatentable over **Frantzen (US 5,741,327)**.

**Regarding claims 25-34, 36-39, 40-43, 44, 48, and 53**, Frantzen discloses a tubular radially expansible metal stent, comprising: a wall comprising an abluminal major wall surface, a luminal major wall surface and a radial wall thickness therebetween, the wall having struts defining through-apertures therein (figs. 12-15); and a plurality of expansible rings arranged adjacent one another along a longitudinal axis of the structure, each of the rings in the shape of a meander defining at least one bridge (120, 60) strut and having a first electrical conductivity (100; column 7, lines 48-50), adjacent rings linked by at least one bridge formed by cooperation between adjacent bridge struts on adjacent rings; each bridge including a portion having a second electrical conductivity (50; column 7, lines 59-60), the bridges distributed throughout the length of the tubular structure and configured and arranged to divide the tubular structure into axially spaced and electrically insulated sections. The bridge comprises inter-engaged joint complementary male/female mating portions that have a frusto-conical shape and arcuate end surfaces (figs. 12-15) in the shape of an "S" or meander. The reduced electrical conductivity portion of the stent is made of nitinol portion (50) which is a modified metal composition of nickel and titanium and comprises a reducing oxide layer (column 7, lines 59-62). The stent may also be stainless steel

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(column 7, lines 50-51). Although this layer is not necessary favorable, it is ultimately formed on the stent therefore meets the structural limitation. Frantzen also teaches using an adhesive to connect two bridges (figs 7-19; columns 7, line 37 – column 11, line 13).

Frantzen fails to disclose wherein the portion having a second electrical conductivity is at least an order of magnitude lower than the first electrical conductivity.

However, Frantzen teaches that the second electrical conductivity (50) come from a portion of the stent that is made of a nickel titanium alloy (column 7, lines 59-60) and that the first electrical conductivity (100) portion is made of gold or silver (column 8, line 5). As is known to one of ordinary skill in the art and stated in the Applicant's specification, titanium alloys have a relatively low electrical conductivity in comparison with gold or silver which has a high conductivity ([0018]).

Given the teachings of Frantzen, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device and method wherein the portion having a second electrical conductivity is at least an order of magnitude lower than the first electrical conductivity. It has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

**Regarding claims 45-47 and 50-52,** Frantzen discloses the invention substantially as claimed as stated above. Frantzen does not explicitly disclose the mounting and laser cutting of the workpiece. However, the Examiner considers it old and well known in the art to mount a tubular structure on a support such as a mandrel, and then to use a laser to cut the pattern of the stent. When a laser is used to create

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the bridge structure, especially the frusto-conical sections, it would be within the purview of one having ordinary skill to depart the laser from the longitudinal axis. This is necessary to create the desired shape. As suggested in Frantzen, (see above), and in the Applicant's disclosure, the use of a laser is generally sufficient to create an oxide layer that will insulate the bridge struts from each other. Also, it is known in the art to apply oxidizing agents to stents to prevent restenosis (see Hastings et al. US 5,951,458 in relevant prior art). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Frantzen's method to include the laser cutting technique. Such a modification provides a means for producing the stent with a high degree of accuracy and precision.

4. **Claims 35 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Frantzen (US 5,741,327)** in view of **Leonhardt (WO 99/43378)**.

**Regarding claims 35 and 49**, Frantzen discloses the invention substantially as claimed as stated above. Frantzen does not explicitly disclose the bridge struts comprising a sleeve. Leonhardt teaches the use of a sleeve to secure portions of stents to each other (Page 6 lines 6-9; fig 2D). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Frantzen's bridges to include Leonhardt's sleeve. Such a modification would provide a means to connect the portions of the device securely to each other.

5. **Claim 54-59** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Frantzen (US 5,741,327)** in view of **Kim (US 6,270,524)** and further in view of **Pacetti (US 6,712,844 B2)**.

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**Regarding claims 54-59**, Frantzen discloses the invention substantially as claimed as stated above. Frantzen does not explicitly disclose pins for connecting the bridge struts. Kim teaches pins to connect adjacent rings (112). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Frantzen's bridges to include Kim's pins. Such a modification would secure the bridges to each other while allowing some degree of flex.

Frantzen and Kim disclose the invention substantially as claimed as stated above. They do not explicitly disclose the pin being made of electrically insulating material. Pacetti teaches the use of non-conducting materials to connect bridges in order to improve the MRI image of the stent (Column 7 Lines 4-26). Ceramics and oxide layers are known insulating materials and would have been obvious based on Pacetti's teaching. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Fogarty and Kim's pins to include Pacetti's insulating material. Such a modification would improve the MRI of the stent.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH A. SIMPSON whose telephone number is 571-270-3865. The examiner can normally be reached on Monday - Friday 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sarah A Simpson/  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
01/12/10